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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,292

09/25/2006

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11/24/2009

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EXAMINER

GUPTA, VANI

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

11/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. *Claims 1, 3, 4, 7, 8, 11, 13, 14, 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Sevick-Muraca et al. (US 7,328,059 B2).*

Regarding Claim 1, Sevick-Muraca et al. (hereinafter *Sevick*) describes a method for detecting a dye bolus injected into the body of a living being, comprising the steps of:

- a. injecting a single dose of fluorescent contrast agent within a short amount of time (or introducing a “dye bolus”) into the body (*col. 3, ll. 22 – 28; col. 7, ll. 6 – 9*);
- b. irradiating an optical excitation radiation into a predetermined region of the body, the excitation radiation being chosen so as to excite a fluorescence radiation of the fluorescent dye (*col. 6, ll. 22 – 25; col. 7, ll. 16 – 17*); and
- c. detecting the fluorescence radiation occurring on the surface of the body (“image of tissue,” *col. 3, ll. 17 – 21*),

With respect to the feature: “wherein the time between the irradiation of said optical excitation radiation and the occurrence of the fluorescence radiation caused by the excitation radiation is measured so as to determine the flight time of fluorescent photons through a tissue between a location of the bolus and the surface of the body,” Sevick

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defines “flight time” or time-of-flight as “the travel time for a photon through multiple scattering media” (col. 13, ll. 56 – 60). Examiner interprets the present feature “tissue between a location of the bolus and the surface of the body” as multiple scattering media. In essence, the time between the irradiation of said optical excitation radiation and the occurrence of the fluorescence radiation caused by the excitation radiation is the same as the flight time of fluorescent photons through a tissue between a location of the bolus and the surface of the body. Sevick determines time-of-flight by measuring frequency and time domain (col. 13, ll. 54 – 67).

Regarding Claim 3, Sevick suggests that time course of the fluorescence radiation is determined with nanosecond time resolution (*col. 14, ll. 35 – 37*).

Regarding Claim 4, Sevick suggests blocking off the frequency of the excitation radiation by filtering for the detection of the fluorescence radiation (*col. 6, ll. 26 – 29*).

Regarding Claim 7, Sevick suggests evaluating detecting fluorescence radiation by assessing the distribution of the measured time of flight photons (see last part of rejection of Claim 1).

Regarding Claim 8, Sevick discusses monitoring and mapping fluorescence characteristics using time-based measurements, including the start of dye bolus detection. This start is represented by the darkening of image regions due to the fluorescing dye that is absorbing radiation. One of the time-based measurements used is “mean ‘time-of-flight’,” or “the mean time between the absorption of an excitation photon and emission of a fluorescent photon” (*col. 13, line 62 – col. 14, line 22*).

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Regarding Claim 11, Sevick discloses a device for detecting a fluorescent dye bolus injected into the body of a living being (**fig. 1, 110; col. 6, ll. 5 – 67**), comprising:

- a. an optical radiation source (*“modulated light source,” 120*) for irradiating an excitation radiation into the body, said excitation radiation being chosen so as to excite a fluorescence radiation of the fluorescent dye (col. 6, ll. 11 – 21);
- b. a detection arrangement (*“detection subsystem,” 140*) for detecting a fluorescence radiation of the fluorescent dye (col. 6, ll. 22 – 51); and
- c. a measurement device (*“processor,” 160*) for detecting a time difference between a time of irradiation of said excitation and a time of detection of said fluorescence radiation (col. 6, line 52 – col. 7, line 53).

Regarding Claim 13, Sevick explains that the detection arrangement disclosed above is designed to detect the time course of fluorescence radiation with nanosecond or picosecond time resolution (*col. 14, ll. 23 – 37*).

Regarding Claim 14, Sevick explains that the detection arrangement disclosed above comprises an optical filter for blocking off the radiation, or for “obtaining a *selected* emission wavelength corresponding to emission of designated fluorophore in tissue” (*col. 6, ll. 26 – 29*).

Regarding Claim 17, Sevick discloses a method for detecting a dye bolus within the body of living being, comprising the steps of;

- a. injecting a fluorescent dye bolus into the body (col. 7, ll. 6 – 7);
- b. irradiating an optical excitation radiation into a predetermined region of the body, the excitation radiation being chosen so as to excite a fluorescence radiation of the fluorescent dye (col. 7, ll. 16 – 17);

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c. detecting the fluorescence radiation on the surface of the body, wherein a high frequency modulated light is used as the excitation radiation and the modulation depth and the phase of the fluorescence radiation are determined (col. 7, ll. 8 – 15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 2 and 12 are rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. (US 7,328,059 B2) as applied to Claim 1 above, in view of Ntziachristos et al. (US 6,615,063 B1).

Regarding claims 2 and 12, Sevick suggests method and apparatus for detecting a (fluorescent) dye bolus injected into the body of a living being, as explained above.

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However, Sevick does not suggest specifically emitting an excitation radiation from an optical radiation source a short pulse with a pulse width in the picosecond range.

Nonetheless, *Ntziachristos et al.* teaches a emitting a excitation radiation pulse with a pulse width in the picosecond range using a fluorescence-mediated molecular tomography system that is capable of detecting a fluorescent dye bolus (*col. 2, ll. 42 – 63; and col. 15, ll. 50 – 54*).

It would be prima facie obvious to modify Sevick with Ntziachristos et al. to include a time-resolved light with short pulse width for shorter time resolution of fluorescence detection.

2. *Claim 9 is rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. (US 7,328,059 B2) as applied to Claim 1 above, in view of Boas (US 6,516,214).*

Regarding Claim 9, Sevick suggests method and apparatus for detecting a (fluorescent) dye bolus injected into the body of a living being, as explained above.

However, Sevick does not suggest specifically that the region irradiated by sid xcitation radiation is at the head in order to examine the brain.

Nonetheless, *Boas* teaches administering a dye bolus into the blood stream of a patient, directing light into the brain of the subject, and detecting light emitted form the brain over time at a detection location (*col. 2, ll. 4 – 26*).

It would be prima facie obvious to modify Sevick with Boas so that one could also use the detection of high and low oxygenation levels by determining decrease or increases in intensity of scattered light for diseased tissue diagnosis (*Boas: col. 1, ll. 45 – 50*).

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3. Claim 10 is rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. (US 7,328,059 B2) as applied to Claim 1 above, in view of Zhao et al. (US 2003/0031628 A1).

Regarding Claim 10, Sevick suggests method and apparatus for detecting a (fluorescent) dye bolus injected into the body of a living being, as explained above.

However, Sevick does not suggest specifically emitting an excitation radiation from an optical radiation source in the area of the lungs.

Nonetheless, *Zhao et al.* describes an experimentation involving first injecting mice suffering from tumors with dye bolus, and then directing optical excitation radiation into the area of the lungs. The tumor areas fluoresced as a result of the application of excitation radiation (para. [0045]).

It would be prima facie obvious to modify Sevick with Zhao et al. so that one could also make use of fluorescent optical tumor imaging (FOTI), which permits real-time observation and monitoring of progression of infection on a continuous basis (*Zhao et al.*: para. [0045]).

4. Claims 5, 6, and 15 are rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. (US 7,328,059 B2) as applied to Claim 1 above, in view of Folestad et al. (US 6,794,670 B1).

Regarding claims 5, 6, and 15, Sevick suggests method and apparatus for detecting a (fluorescent) dye bolus injected into the body of a living being, as explained above.

However, Sevick does not suggest specifically detecting the excitation radiation diffusely reflected from the body simultaneously and in parallel to detecting the fluorescence radiation from the tissue; and accomplishing this in a time-resolved manner.

Nonetheless, *Folestad et al.* discusses detecting the radiation reflected from the sample as well as the diffusely backscattered radiation by a single lens (**fig. 1b, L4'**); and accomplishing it in a time-resolved manner (*col. 6, ll. 35 – 54*).

It would be prima facie obvious to modify Sevick with Folestad et al. so that one could accomplish both tasks in time-resolved manner using one component of the same apparatus, which would take up less resources (cost, infrastructure, material, etc.)

Response to Arguments

1. Applicant's arguments, filed July 20, 2009, with respect to the rejection(s) of claim(s) 1 – 3, 5 – 8, 11 – 13 and 16 under 35 U.S.C. 102(e) as being anticipated by Flower et al. (US Patent 7,364,574); claims 9,10, and 15 under as 35 U.S.C. 103(a) as being obvious over Flower et al.; and claims 4 and 14 rejected under 103(a) as being obvious over Flower et al. in view of Schiler (US Patent 5,400,791) have been fully considered and are persuasive.

Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection have been as follows: claims 1, 3, 4, 7, 8, 11, 13, 14, 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Sevick-Muraca et al. (US Patent 7,328,059 B2); claims 2 and 12 are rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. in view of Ntziachristos et al. (US 6,615,063 B1); claim 9 is rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. in view of Boas (US 6,516,214); claim 10 is rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. in view of Zhao et al. (US 2003/0031628 A1); and claims 5, 6, and 15 are rejected under 35 USC 103(a) as being unpatentable over Sevick-Muraca et al. in view of Folestad et al. (US 6,794,670 B1).

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2. Examiner has noted amendments to Specification and has withdrawn objections to the Specification.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768